HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP)

A STUDY FOR MEDICAL DEVICE MANUFACTURING

HACCP Team
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Revised: 2/8/01

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP):

A Feasibility Study for Medical Device Manufacturing

INTRODUCTION

A reengineering project in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is proposing to conduct a feasibility study of medical device manufacturers using Hazard Analysis and Critical Control Points (HACCP) principles. The information derived from the study will help CDRH determine the advantages and potential disadvantages in the use of HACCP principles for: (1) premarket submissions, product and process review; (2) identifying and correcting product and process problems for devices currently on the market; and (3) streamlining inspections.

Pre-study data suggests that the use of HACCP principles will assist CDRH in the review of premarket submissions by providing a structured and systematic risk-based presentation (roadmap) of design controls and manufacturing processes. HACCP is a science-based method for manufacturers to identify, process, and document critical design outputs, control, monitoring and verification of those critical products and product related processes. Thus far, three medical device manufacturers implemented HACCP and have reported positive results through the various media, i.e., published articles, press, video, etc. CDRH and other FDA personnel may be trained to perform HACCP inspections. HACCP principles provide a logical and structured inspection method to use for "product directed inspections".

Other industries, such as the seafood industry, use HACCP principles. The agency's Center for Food Safety and Applied Nutrition (CFSAN) and the Department of Agriculture, and worldwide organizations, such as Codex Alimentarius and the European Union include HACCP in their manufacturing assessment programs.

This document explains, in detail:

1. The role and responsibilities of the industry and government during the study.
2. Eligibility criteria for participation in the study.
3. What to expect from "on site" visits by FDA.
4. Protocol design and data analysis.

NOTE: THIS STUDY DOES NOT PRECLUDE ANY MANUFACTURER FROM IMPLEMENTING A HACCP SYSTEM/PLAN. THE STUDY HAS BEEN LIMITED DUE TO RESOURCE CONSTRAINTS ONLY.

DEFINITIONS

Documentation Package - Information provided by the firm to the agency that details the HACCP plan and training to be used by the firm in the study.

Firm - A medical device manufacture whose responsible agent has signed an agreement with CDRH to participate in the HACCP study.

HACCP Administrator - A trained person, designated by the firm, to coordinate the development of the HACCP plan, lead HACCP team activities, and provide liaison between CDRH and the firm during the study.

HACCP Plan - The written document based upon the principles of HACCP, which delineates procedures to be followed to assure control of a specific product and a specific process.

HACCP System - The firm's HACCP related activities, including prerequisite programs, HACCP training and HACCP plan.

Prerequisite Programs - Pre-established programs in place at the firm before implementation of HACCP, such as; design control; quality systems; sanitary control over facilities, personnel, equipment; production and processing operations; compliance with all applicable FDA regulations.

Site Team - The CDRH/other FDA personnel assigned to a specific firm to conduct site evaluations during the study.

Study Agreement - An agreement signed by CDRH and a firm that identifies the respective responsibilities of CDRH and the firm during their participation in the HACCP study (see Attachment A).

ROLE RESPONSIBILITIES DURING THE HACCP FEASIBILITY STUDY

HACCP has achieved international recognition as a management tool for developing a rational and scientifically based system to minimize impact from manufacturing processes on product safety and performance. Key elements of a HACCP system consist of the following:

1. Identification of all potential hazards to safety and performance and corresponding preventive measures necessary for their control, for both the product and the process;

2. Identification and effective control of these hazards at critical steps during the manufacturing process, called critical control points (CCP); and

3. Documentation that this control is maintained on a continuing basis.

The main advantage offered by a HACCP system is that defects compromising the safety and performance of medical devices can be identified more quickly at specific points in the manufacturing process. This means corrective actions can be taken sooner. By contrast, traditional control systems rely more on the government and industry to conduct infrequent inspections and end product testing to identify defects.

Government's Role in the Study

HACCP is designed to enhance the safety and performance of medical devices, and will not replace existing regulations, which will continue to apply. CDRH's role under HACCP is to ensure that HACCP plans are appropriately designed, implemented and maintained, via on-site evaluations of the firm's documentation (HACCP records).

Industry's Role in the Study

HACCP is a tool available to industry to strengthen their control over medical device safety and performance along the entire manufacturing chain from design, receipt and storage of raw materials, to storage, distribution and use of the end product. To effectively use this tool industry must: (a) ensure management commitment to HACCP; (b) develop, implement, and maintain prerequisite and quality system regulation programs, and HACCP plans; (c) maintain records of HACCP controls and prerequisite quality system regulation program implementation; and (d) ensure that staff at all levels are appropriately trained and qualified in their respective areas of responsibility. Industry should review and

update HACCP plans to conform to new developments and changes in technology, product formulation, processing, and equipment.

Voluntary Approach

This HACCP study is a **voluntary, non-regulatory program.** Data voluntarily submitted to CDRH will be considered confidential because FDA recognizes that these documents contain trade secrets. On site visits are called "evaluations" in order to distinguish them from inspections, which are done under FD&C inspections authority. **Thus, neither a FDA-482 Notice of Inspection, nor a FDA-483 List of Observations, will be issued.**

Training for Regulatory Personnel

The CDRH/Field site team members are trained in the principles of HACCP and in conducting evaluations at study firms. This training includes conducting a hazard analysis, determination of critical control points, differentiation between HACCP and other quality control systems, and familiarity with changes in the role of the regulator under the HACCP system.

ELIGIBILITY CRITERIA FOR PARTICIPATION IN THE HACCP FEASIBILITY STUDY

Management Commitment

The senior management of participating firms should provide a clear and visible commitment to the HACCP study. The firm may demonstrate this commitment by the following activities; signing an agreement to participate, appointing a HACCP Administrator, providing adequate authority and resources to HACCP participants, and implementing prerequisite programs, such as training and HACCP plan implementation, in a timely manner.

HACCP Administrator

The HACCP Administrator should be trained in HACCP principles and acknowledged as responsible for oversight of the HACCP program. The HACCP administrator's duties during a study include the following:

1) leading the HACCP team and functioning as the contact point between government and industry during the development and implementation phases;
2) confirming that the prerequisite programs are in place;

3) validating the HACCP system on behalf of the firm and preparing the documentation package for CDRH;
4) ensuring that the HACCP plan continues to be representative of actual operating conditions by making necessary changes to conform with alterations to the plant, process or product; and
5) performing periodic audits of the HACCP plan to confirm that the plan is being fully implemented, and is effectively controlling medical device safety and performance hazards.

Management Responsibility for Training

Management is responsible for ensuring that staff is adequately trained in HACCP development and implementation. The designated HACCP Administrator, as well as key line employees, should receive this training.

Training may be obtained through participation in CDRH and/or industry sponsored HACCP training sessions or in HACCP seminars provided periodically by trade and professional associations.

Training of the HACCP Administrator and Team

The HACCP Administrator needs to have a thorough understanding of:

- performance of a hazard analysis and determination of critical control points;
- requirements for prerequisite programs;
- preparation and implementation of a HACCP plan in the establishment; and
- verification that the HACCP plan has been successfully implemented, including a timeframe for revalidation.

Many industry personnel have attended HACCP training programs. Study participants are not expected to repeat the training; however, the firm needs to ensure that the training received was sufficient and consistent with the principles of the Medical Device HACCP Training Curriculum.

Training of Line Employees

Line employees and floor staff should be trained such that they understand their specific functions and duties, and how these are to be performed under a HACCP system/plan. They are not expected to have a comprehensive knowledge of HACCP, but they should be trained to understand, at a minimum:

- the importance of the critical control points (CCP) for which they are responsible;
- the critical limits associated with a given CCP;
- the procedures for monitoring these critical limits;
- the corrective actions to be taken if there are deviations from the critical limits; and
- the records that are to be kept.

Prerequisite Programs

Establishing and maintaining prerequisite programs must be completed prior to developing a HACCP program. The principal prerequisite programs necessary to have in place before HACCP can be developed are those described within the quality system regulation.

DEVELOPING AND MAINTAINING HACCP PLANS

Firm's need to develop, implement and maintain HACCP plans to participate in the study. A participating firm needs to select one product and production line/process to use as the subject of the study. We do, however, encourage firms to extend the HACCP program to other medical devices and processes. The experience gained in the study may provide a basis to refine the application of HACCP to other production operations

Documentation Package

Firms who participate in the study need to develop, in consultation with CDRH, a complete, well-documented HACCP program.

A complete information package should be signed by senior management and submitted to the Office of Compliance, CDRH. The prerequisite program should be fully developed, and the HACCP plan validated and documented by the firm. The firm's staff should be trained to implement the HACCP plan. The names and qualifications of the HACCP Administrator and team members, along with their training related to HACCP, should be included.

HACCP Plan

For each HACCP plan, the following information should be submitted:

1) HACCP team description
2) product/process type description
3) intended use and end user
4) process flow diagram
5) plant schematic diagram
6) hazard analysis
7) critical control point determination
8) critical limits
9) monitoring procedures
10) corrective actions
11) verification procedure
12) record keeping procedures and samples of records
13) current product labeling (for IVDs product insert)

Further details on the nature and extent of the specific information required may be found in the Medical Device HACCP Curriculum Manual.

CDRH REVIEW OF HACCP SYSTEM

A review of the firm's HACCP plan will be conducted by CDRH which can address proper application of HACCP principles, use of sound science, adequate identification of hazards, appropriate selection of CCPs and appropriateness of critical limits, monitoring procedures, corrective actions, verification procedures, and record keeping systems. Any changes required or suggested will be provided to the HACCP Administrator for appropriate follow-up.

Communicating Review Results

CDRH will provide comments to the firm's HACCP Administrator after completing a review of the firm's HACCP plan. The firm will need to determine whether any modifications should be made to their plan. Any modifications should be discussed with the site team and documented. The firm may modify its HACCP documentation package and verify the implementation of the modifications prior to the start of the study.

Start Up Date for the Study

CDRH and the firm will agree upon a date for the study to commence after any modifications to the firm's HACCP program have been implemented. This date will be entered into the CDRH/firm HACCP study agreement.

Site Evaluation of HACCP Programs

HACCP Evaluation Team

A HACCP site evaluation team will be assigned to each study plant. An attempt will be made to assign the same team members to a given firm throughout the duration of the study.

Start Up Site Evaluation

A start up site evaluation may be conducted approximately eight (8) weeks after the firm's start up date. The eight-week period would allow the firm to begin compiling HACCP records. The site visit would be scheduled for two days. The start up site evaluation would verify that the firm's HACCP plan is being effectively implemented on a continuing basis, and that the HACCP plan provides necessary medical device safety and performance controls.

Collecting HACCP Data

Each firm needs to maintain the following HACCP records and make them available to CDRH for review during site visits:

- the HACCP plan;
- the hazard analysis;
- examples of records used for monitoring;
- copies of verification audits;
- daily monitoring records;
- corrective action logs; and
- current product labeling (and product inserts).

Copies of additional records may be requested when the firm documents information for the purposes of the HACCP study. On site observations of

activities, conditions in selected operational areas, interviews with designated HACCP personnel will also contribute to the HACCP assessment.

Discussing CDRH's Findings

CDRH will discuss the team's findings with the firm at the conclusion of the site evaluation. CDRH may amend its findings based upon additional information provided by the firm. The discussion provides an opportunity to reach an agreement on the findings. CDRH will note any disagreements and provide an explanation.

Resolving Disagreements

Any disagreements concerning the data collected by CDRH, such as evaluation findings, follow-up action, or modifications to the HACCP plan, should be discussed during the site evaluation. CDRH and the firm need to make a concerted effort to resolve any disagreement.

Modifying the HACCP Plan

Once CDRH and the firm agree on the site evaluation findings, agreement should be reached on the proposed modifications to the HACCP plan to resolve the issue. A time frame for implementation should be included in the discussion.

The firm should notify CDRH if any proposed modification to its HACCP plan affects a critical element that may directly mpact the safety and performance of the product. Otherwise, the modifications will be reviewed during the next site evaluation. Contact Adrianne Galdi, HACCP Team Leader at 301- 594-4586 ext. 141 or Joseph Salyer at 301- 594-4586 ext. 175 on any follow-up action items.

Final Site Evaluation

CDRH will conduct a final site evaluation at a mutually agreed upon time, which will be approximately 10 months after the start of the study. The study will be completed when its goals have been accomplished (see Protocol Design and Data Analysis).

In preparation for the final site evaluation, CDRH will request the firm to review previous site evaluation reports, and be prepared to discuss trends and overall findings with its site team. Findings from the final site evaluation will be discussed with the firm along the lines of previous site evaluations.

TERMINATION OF THE HACCP AGREEMENT

The agreement stipulates that either party can terminate participation in the study at any time. CDRH is willing to render assistance to a firm encountering difficulties with implementing its HACCP plan, so long as that firm remains committed to the plan.

PROCESSING OF INFORMATION DERIVED FROM THE STUDY

Analysis of Trends

CDRH and the firm's HACCP team will review all site evaluation findings, from the beginning of the study until the end. Agreement should be established regarding trends and findings that will be useful in assessing the firm's HACCP plan. The issues to be analyzed include, but are not limited to:

- Achievements and problems encountered by the firm in developing an effective HACCP plan;
- Successes and challenges the firm encountered in implementing and operating under HACCP;
- Type and extent of assistance requested and received from CDRH or others, and whether this assistance was helpful;
- Training that was useful;
- Appropriate role of consumer complaints in verification procedures;
- How best to measure the effectiveness of HACCP; and
- Costs incurred by the firm in using HACCP.

Assessing Benefits and Deficits from HACCP

CDRH and the firm will discuss benefits and deficits resulting from operation under HACCP, which may include:

1. Product safety,
2. Product quality,
3. Shelf life of the product,
4. Product liability premiums,
5. Operational costs,
6. Productivity,
7. Employee morale, and
8. PMA and 510(k) submissions and clearance.

CDRH will work with the firm in developing as much information as possible to document these and any other benefits and deficits.

PROTOCOL DESIGN AND DATA ANALYSIS

Purpose of the Study

- This study will provide FDA and industry with an opportunity to accrue practical experience with using HACCP as a risk management tool.

Study Objective

- To determine the advantages and potential disadvantages of the use of HACCP as a risk management tool for: (1) premarket, product and process reviews; (2) identifying and correcting product and process problems for devices currently on the market; and (3) streamlining inspections.

Assumptions

- Successful completion of HACCP
- Standardization of training procedures
- Continuity of management commitment
- Distribution free and low numbers

Data Analysis Stratification

- Two study populations

    (1) New products.

        a. Devices that are new to the market as well as the manufacturer.

    (2) Older products.

        a. Devices that are new to the manufacturer, but are not new to the market.
        b. Established devices that are not new to the market or the manufacturer.

Study Population (10 volunteer firms, 2 groups of 5 each)

- Group 1 - New Products
- Group 2 - Older products

Advantages and disadvantages of using HACCP may also be revealed with study data based on manufacturing profile classes (processes). An additional stratification of the study population may include manufacturing processes. HACCP is focused on manufacturing processes and the majority of general medical devices are produced using processes relating to metals fabrication and assembly, plastic or rubber fabrication and assembly, and electronic assembly. (See Attachment B for a complete List of Manufacturing Processes).

Outcome Parameters

Group 1 - New Products
- Length of inspection time
- Savings in time, resources, personnel, etc.
- Cost associated with quality control
- Number of product reworks
- Number of products destroyed
- Number of complaints/MDRs received
- Time to determination of PMA fileability
- Other

Group 2 - Older products
- Length of inspection time
- Number of product recalls
- Savings in time, resources, personnel, etc.
- Cost associated with quality control
- Number of product reworks
- Number of products destroyed
- Number of complaints/MDRs received
- Number of near misses
- Cost of scrap
- Other

Note: The above response variables are a function of successfully completing HACCP. Some of the other items listed under Analysis of Trends (i.e., cost to company, changes to plan, deviations from CCPs, training problems, production problems, etc.) also represent criteria which would be used to determine the successful implementation of the HACCP plan.

Statistical Methods/Tools

There are many ways to approach the analysis for this study. All are exploratory in nature and are dependent on the final design of the study and the scales of measurement. The exploratory data analysis primarily consists of generating graphic presentations such as scattergrams, histograms, box plots, and stem leafs to look at general distributions and trends. The following are just a few of the parametric and non-parametric inferential tools that would seem to be appropriate for the analysis of those manufacturers who do successfully complete the HACCP plan/system:

- Pre-Post.
- Test Design where baseline assessments are contrasted to assessments after intervention, (i.e., HACCP plan/system).
- Time-to-event analysis, (i.e., logistic regression) for time to PMA filing.
- Tests of association.

The next list represents methods, which would seem to be appropriate for the analysis of those manufacturers who do not successfully complete the HACCP system/plan:

- Step-wise least squares regression to eliminate non-informative variables from the model.
- Cost/benefit analysis.
- Time-to-event analysis, (i.e., logistic regression) for time to termination of participation or time to detection of defects or time to implementation of corrective action.
- Random effects model for longitudinal repeated measures, (i.e., contrasting findings at each audit or site visit).
- Matched pairs t-test.
- Sign or McNemar test.

The final analysis might be devoted to determining what manufacturer characteristics or what elements of the HACCP process were associated with the successful implementation or not of the HACCP plan/system.

Final Report

FDA will prepare a summary report of the study as a whole. This report will be made available to the general public.

HACCP SYSTEM FAILURE

All failures should be identified and documented by the HACCP Administrator where the firm failed to meet its HACCP plan requirements. Examples of failures would include items such as not monitoring a critical control point (CCP) or not taking corrective action, as defined in the HACCP plan.

Participating firms need to review consumer complaints as part of their HACCP plan verification procedures and document the corrective actions taken. The site team will review the procedures concerning consumer complaints and attempt to see whether complaints are managed effectively.

Where a failure is associated with a significant impact on safety and performance, FDA will request that the firm take appropriate voluntary corrective action. However, where there is a risk posed to the public health, participation in the HACCP program does not change the firm's obligation concerning other existing FDA regulations affecting the firm's device.

ATTACHMENT A

AGREEMENT
BETWEEN

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
AND

(INSERT COMPANY NAME & ADDRESS)

RELATIVE TO PARTICIPATION IN A FEASIBILITY STUDY BASED UPON HAZARD ANALYSIS CRITICAL CONTROL POINTS (HACCP) PRINCIPLES

BACKGROUND

Under the reengineering project initiative in the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH), premarket medical device inspections were selected as a candidate for using Hazard Analysis Critical Control Points (HACCP) principles. A feasibility study has been proposed to test HACCP on the medical device industry. This Study Agreement, signed by the CDRH and a medical device manufacturer, identifies the respective responsibilities of CDRH and the manufacturer during their voluntary participation in the HACCP study (the Study).

[Insert Company Name] (the "Participant"), recognizes the potential benefit to itself, the FDA, the medical device industry, and the public of such a feasibility Study. This Study offers the industry participant an opportunity to work with CDRH in a collaborative manner to determine how best to apply HACCP principles in medical device manufacturing facilities, and to engage in a scientific dialogue with CDRH, while protecting the confidentiality of Participants information and the results of its participation in the Study

PURPOSE AND GOALS

The feasibility Study is intended to provide information that CDRH can use in deciding whether to use HACCP principles for: (1) premarket submissions, product and process review; (2) identifying and correcting problems for devices currently on the market that have performance issues; and (3) streamlining premarket inspections. The Study data includes insights into the problems, costs, and benefits of developing and implementing HACCP for manufacturers that produce a variety of medical devices. The Study is also intended to provide CDRH with experience in working with HACCP and information as to whether HACCP is practical for the medical device industry as a whole. It is projected that the Study will operate approximately ten (10) months after the start date at each volunteer manufacturer.

RESPONSIBILITIES

CDRH is responsible for:

- reviewing the Participant's HACCP program to ensure that the HACCP plan and employee training programs are suitable for the feasibility Study.

- designating a HACCP Study Site Team to evaluate the Participant's HACCP program at the plant;

- conducting an initial evaluation of the Participant's HACCP program approximately eight (8) weeks after the mutually acceptable Study program start date to confirm that operations at the Participant's company are consistent with the plan; Such evaluation is considered a voluntary, non-regulatory program. Thus, neither a FDA-482 Notice of Inspection, nor a FDA-483 Inspectional Observations will be issued;

- conducting evaluations of the Participant's HACCP program after the initial evaluation as needed, to confirm that the HACCP plan continues to be properly implemented and appropriate for the manufacturer's operation;

- conducting a final evaluation of the Participant's HACCP program to close out the program at the Participant's company;

- preparing a final consolidated confidential summary evaluation report of the Study program;

- protecting any trade secrets or confidential information and any results of the Study produced by Participant's participation in the Study, in accordance with 21 CPR 20.61.

Participant is responsible for:

- implementing the HACCP program at the designated production facility, making the production facility available for site evaluation by the HACCP Study Site Team upon advanced written notice to Participant by CDRH, and making qualified personnel available to answer inquiries;

- maintaining all records required by the Participant's HACCP plan including hazard analysis, preventive measures, critical control point and critical limit documentation; monitoring records of preventive measures associated with critical control points; corrective action reports; and verification records including consumer complaints relevant to the HACCP plan; and making those records available to the HACCP Study Site Team personnel for review:

- reviewing *and* revising the HACCP plan *as* necessary, *and* providing additional HACCP training to key employees, as necessary; and

- providing reasonably available information regarding cost and benefit, training, and environmental impacts regarding the Participant'' HACCP program implementation, including changes in training, materials production, and operation costs; changes in plant production and safety control efficiency; and any correlation between training and level of HACCP effectiveness that will help FDA assess the impact of the HACCP approach to medical device safety and effectiveness.

- Participant may refuse to provide CDRH with any information requested by CDRH if Participant believes, in good faith, that such information is not relevant to the purpose of the Study. Participant will not suffer any adverse consequences, in connection with the Study or otherwise, for exercising its right to refuse requests for information hereunder.

This Agreement:

- will remain in effect until the earlier of (I) the HACCP Study program at the Participant's company is completed, after approximately ten (10) months, (ii) as determined by FDA in consultation with the Participant's management, or (iii) until terminated as provided below;

- can be terminated if during the course of the evaluation, objectionable conditions are observed, or if there are extenuating circumstances, which preclude FDA from continuing with the pilot.

Correspondence regarding this Agreement should be directed to the following:

CDRH	**PARTICIPANT**
Adrianne Galdi Director, Division of Enforcement 1 HACCP Reengineering Team Leader 2094 Gaither Road CDRH/HFZ-320 Rockville, MD 20850	Contact Person Company Name Company Address

COMPLETE AGREEMENT

It is agreed that there are no other agreements or understandings, either oral or written, between CDRH and Participant affecting this Agreement and that no term, provision, or condition set forth in this Agreement can be altered, amended, changed or waived in any respect except by written agreement signed by CDRH and Participant.

ASSIGNMENT

CDRH may not assign this Agreement or any of its rights or obligations under this Agreement without the prior consent of Participant.

FORCE MAJEURE

Neither CDRH nor Participant shall be liable for any delay or failure of performance if and to the extent such delay or failure is caused by circumstances beyond its reasonable control and that by

the exercise of due diligence it is unable to prevent, provided that the non-performing party uses its best efforts to overcome the same.

In the event any terms of this Agreement is or becomes or is declared to be invalid or void by any court of competent jurisdiction, such term or terms shall be null and void and shall be deemed deleted from this Agreement, and all the remaining terms of the Agreement shall remain in full force and effect.

NON-WAIVER

The failure of either party in any one or more instances to insist upon strict performance of any of the terms and conditions of this Agreement shall not be construed as a waiver or relinquishment, to any event, of the right to assert or rely upon any such terms or conditions on any future occasion.

AUTHORITY TO EXECUTE

Each person signing this Agreement hereby certifies that he or she is duly authorized to execute this Agreement on behalf of the respective party.

IN WITNESS WHEREOF, the parties have executed this Agreement in duplicate, effective as of the day and year first written below:

CDRH	**PARTICIPANT**
By:	**By:**
Print Name	**Print Name:**
Title:	**Title:**
Date:	**Date:**

The agreed-upon start date for the Study to begin at Participants facility is,

ATTACHMENT B
LIST OF MANUFACTURING PROCESSES

- **BBP Blood and Blood Products, Unlicensed (human and animal)**
- **CCR Clinical Chemistry Reagents (includes diagnostic tapes, Sticks, etc.)**
- **COH Computer Hardware**
- **COS Computer Software**
- **CSP Chemical Sterilization**
- **ELE Electronic Assembly**
- **FSP Filtration Sterilization**
- **GLA Glass or Ceramics Fabrication and Assembly**
- **GSP Gas (ETO, Propylene Oxide) Sterilization**
- **HCP Hematology and Coagulation Products**
- **HSP Dry Heat Sterilization**
- **MED Media (includes microbiological and tissue culture growth media and accessories, including ingredients)**
- **MIS Not Elsewhere Classified**
- **MTL Metals Fabrication and Assembly**
- **OPT Optics Fabrication**
- **PBM Processed Biological Material**
- **PRF Plastic or Rubber Fabrication and Assembly**
- **RIP Radioimmunoassay Products**
- **RSP Radiation Sterilization**
- **SIP Serological and Immunological Products (includes Bacterial typing rheumatoid factors, etc.)**
- **SSP Steam Sterilization**
- **TSP Fractional (Tyndallization) Sterilization**
- **TXT Textile Fabrication and Assembly**
- **WOD Wood Fabrication and Assembly**
- **WSP Water Sterilization**